

DEC 9 2005

**510(k) Summary**

Submitter: Gambro Renal Products  
10810 West Collins Avenue  
Lakewood, Colorado 80215

Contact: Thomas B. Dowell, Manager, Regulatory Affairs  
  
Phone: 303-231-4094  
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Date prepared: June 6, 2005

Device name: Gambro Polyflux 6H Capillary Dialyzer

Common name: Hemodialyzer / Filter

Classification name: High Permeability Hemodialysis System Accessory (876.5860)

**Predicate Devices:**

Polyflux 140H, 170H, 210H	Hemodialyzer / Filter	K030592
100 HG	Hemodialyzer / Filter	K904566

**Device Description:**

The Gambro Polyflux 6H Capillary Dialyzers/Filters, labeled for single use, have the same design, materials, intended use and function as other hemodialyzers / filters currently marketed in the United States.

These device is intended for use in hemodialysis, hemodiafiltration and hemofiltration for the treatment of acute and chronic renal failure.

Considering blood flow, body weight and extracorporeal blood volume, the Polyflux 6H is intended for pediatric indication. The membrane used in this device is a blend of polyarylethersulfone (PAES), PVP, and Polyamide, which is identical to the membrane used in the Gambro Polyflux H single use hemodialyzers cleared under 510(k) Notification (K030592) and the Polyflux L dialyzers cleared under 510(k) Notification (K010985).

Blood enters a blood inlet port where it is distributed to the hollow fibers. The patient's blood traverses the inside of the hollow fibers and exits the device via a blood exit port. By means of a hydrostatic pressure or transmembrane pressure which is created by a combination of positive and negative pressures across the membrane, plasma water along with certain lower and middle molecular weight solutes pass through the membrane and into the dialysate or filtrate compartment of the device. Uremic toxins and waste products are removed from the patient's blood in this device by means of both diffusion and convection through the membrane and into the countercurrent flowing dialysis solution during hemodialysis. The dialysate exits the devices via a dialysate outlet port.

**Indications For Use:**

The Polyflux 6H is intended for chronic and acute applications in hemodialysis, hemodiafiltration and hemofiltration on small patients including pediatric indications, considering blood flow, body weight and extracorporeal blood volume.

**Technological Characteristics:**

The proposed device configurations have the same technological characteristics and are similar in design, function, composition, and operation, to the currently marketed configurations.

**Summary of Non-Clinical Tests:**

N/A

**Summary of Clinical Tests:**

N/A

**Conclusion:**

Testing performed on the Gambro Polyflux Dialyzers / Filters indicates that they are safe, effective and perform as well as the predicate devices, when used in accordance with the instructions for use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 9 2005

Mr. Thomas B. Dowell  
Regulatory Project Manager  
Gambro Renal Products  
10810 W. Collins Avenue  
LAKEWOOD CO 80215

Re: K051520  
Trade/Device Name: Polyfulx 6H Capillary Dialyzer / Filter – Pediatric Labeling  
Regulation Number: 21 CFR §876.5860  
Regulation Name: High permeability hemodialysis system  
Regulatory Class: II  
Product Code: KDI  
Dated: November 29, 2005  
Received: December 2, 2005

Dear Mr. Dowell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Indications for Use Statement**

**510(k) number:  
(if known)**

K051520

**Device Name:**

Polyflux 6H Capillary Dialyzer / Filter – Pediatric Labeling

**Indications for Use:**

**The Polyflux 6H is intended for chronic and acute applications in hemodialysis, hemodiafiltration and hemofiltration on small patients including pediatric indications, considering blood flow, body weight and extracorporeal blood volume**


Prescription Use   X    
(Per 21 CFR 801 Subpart D)

AND / OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal, and  
Radiological Devices  
510(k) Number K051520